UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF NEW YORK

THE UNITED STATES OF AMERICA and the STATE OF NEW YORK *ex rel.* Jane Doe,

Plaintiffs,

v.

FLAUM EYE INSTITUTE and THE UNIVERSITY OF ROCHESTER MEDICAL CENTER,

Defendants.

QUI TAM COMPLAINT
AND
DEMAND FOR A JURY TRIAL

FILED UNDER SEAL
PURSUANT TO
31 U.S.C. §§ 3729 *et seq.*

Civil Action No.
5:15-CV-266
MAD/TWD

Relator Jane Doe brings this action in the name of the United States of America and the State of New York, by and through her undersigned attorneys Thomas & Solomon LLP, and alleges as follows.

INTRODUCTION

1. This is a civil fraud action to recover damages and penalties on behalf of the United States of America and the State of New York (individually and collectively, the "Government") arising from false claims and statements made and presented by the Flaum Eye Institute and the University of Rochester Medical Center (collectively, the "Defendants") in violation of the Federal False Claims Act ("FCA"), 31 U.S.C. §§ 3729 *et seq.*, and the New York State False Claims Act, N.Y. FIN. LAW §§ 187 *et seq.* ("NYSFCA").

2. Defendants are health care service providers that participate in and receive reimbursement and other payments from programs funded by the Government, including Medicaid and Medicare.

3. Defendants' wrongful practices include improperly and knowingly submitting

false claims for reimbursement to Government Programs, including Medicare and Medicaid. Specifically, defendants schemed to defraud the Government by: (1) systemically upcoding "Modifier 25" codes; (2) improperly diverting 340B drugs that were purchased at discounted prices under a Medicaid subsidy program and improperly billing the place of service to make the administration of such drugs look permissible; (3) improperly billing for "Premium IOL" services to offset the purchase of a Femto laser; and (4) medically unnecessary cataract surgeries performed by Dr. Yousuf Khalifa that defendants later identified as known overpayments yet have failed to report to the Government as known overpayments.

4. Defendants have improperly and knowingly presented claims for payment to the Government that, upon information and belief, the Government would not have paid but for Defendants' false statements.

5. The FCA permits any person having information regarding a false or fraudulent claim for payment from Government funds to bring an action for himself as the Relator and for the Government and allow him to share in any recovery.

6. Based on the foregoing provisions, as well as similar provisions of the NYSFCA, Relator Doe asserts violations of Federal and State law in connection with false claims made by Defendants in connection with Medicare and Medicaid.

7. Relator Doe seeks to recover all available damages, civil penalties, and all other relief available for expenditures impacted by Defendants' fraud, including treble damages and penalties under the FCA, the NYSFCA, and Federal and State whistleblower provisions. Damages owed to the Government include, but are not limited to, the full value of all reimbursements pursuant to Government Programs that the Government would not have paid but for Defendants' false claims and certifications.

8. Upon information and belief, the Government would not have paid Defendants' claims had it been aware of the falsity of Defendants' claims and certifications.

STATUTORY BACKGROUND

9. The False Claims Act provides liability for any person (i) who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval"; (ii) who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;" or who otherwise improperly makes false statements to the Government. 31 U.S.C. § 3729(a)(1)(A)-(G). The False Claims Act further provides that any person who violates the Act "is liable to the United States Government for a civil penalty ... plus 3 times the amount of damages which the Government sustains because of the act of that person." 31 U.S.C. § 3729(a); *see* 28 C.F.R. § 85.3(a)(9).

10. The FCA defines "knowing" as having actual knowledge that the information is false, or acting with a deliberate ignorance of, or reckless disregard for, the truth or falsity of the information. 31 U.S.C. § 3729(b). No proof of specific intent to defraud is required. *Id.*

11. The FCA permits any person having information regarding a false or fraudulent claim for payment from Government funds to bring an action for herself as the Relator and for the Government and allow her to share in any recovery.

12. The New York FCA has analogous *qui tam* provisions and procedures described above with respect to the federal FCA. N.Y. State Fin. § 190.

13. The NYSFCA, § 189(1) imposes liability on anyone who, *inter alia*: "(a) knowingly presents, or causes to be presented a false or fraudulent claim for payment or approval; (b) knowingly makes, uses, or causes to be made or used, a false record or

statement material to a false or fraudulent claim; (c) conspires to commit a violation of [the NYSFCA] . . ."

14. The NYSFCA defines "knowing" as having actual knowledge of the information, or acting with a deliberate ignorance of, or reckless disregard for, the truth or falsity of the information. N.Y. State Fin. Law § 188. Like its federal counterpart, no proof of specific intent to defraud is required. *Id.*

JURISDICTION AND VENUE

15. This Court has jurisdiction over this action pursuant to 31 U.S.C. § 3732, conferring jurisdiction for actions brought pursuant to 31 U.S.C. §§ 3729 and 3730, and pursuant to 28 U.S.C. § 1331, conferring jurisdiction over all civil actions arising under the laws of the United States.

16. Pursuant to 28 U.S.C. § 1367, this Court has supplemental jurisdiction over the claims brought under New York law as those claims form part of the same case or controversy as the federal claims.

17. Venue is proper in this District because Defendants transact business in this judicial district, and acts proscribed by 31 U.S.C. § 3729 have been submitted to the Government in this District. Therefore, venue is proper within the meaning of 28 U.S.C. § 1391(b) and 31 U.S.C. § 3732(a).

18. Relator shall serve a copy of this Complaint upon the United States and the State of New York. Relator will also serve upon the United States and the State of New York a written disclosure statement setting forth and enclosing all material evidence and information she possesses, pursuant to the requirements of 31 U.S.C. § 3730(b)(2).

THE PARTIES

19. The plaintiffs in this action are the United States of America and the State of New York, suing on their own behalf and on behalf of the United States Department of Health and Human Services ("HHS") and HHS' component agency, the Centers for Medicare and Medicaid Services ("CMS").

20. Relator Jane Doe is a resident of the State of New York and is directly familiar with the facts and circumstances contained within this Complaint. Relator is an original source of the facts and information hereinafter set forth concerning the activities of the Defendants. The facts averred herein are based upon the direct, independent and personal knowledge, and also upon various documents in the possession of the relator.

21. Defendant University of Rochester Medical Center is an integrated health care system that comprises Strong Memorial Hospital, The University of Rochester School of Medicine and Dentistry, including its faculty practice (University of Rochester Medical Faculty Group); Strong West in Brockport; Highland Hospital; Thompson Health; Golisano Children's Hospital; James P. Wilmot Cancer Center; School of Nursing; Eastman Dental Center; Visiting Nurse Service of Rochester and Monroe County; Highlands at Pittsford; and Highlands at Brighton.

22. Defendant University of Rochester Medical Center maintains a Department of Ophthalmology that is adjacent to the Flaum Eye Institute at 210 Crittenden Blvd., Rochester, New York.

23. Defendant Flaum Eye Institute is a private office-based provider that provides ophthalmology services in the Greater Rochester area and in the Geneva, New York area.

24. Defendant Flaum Eye Institute is located at 210 Crittenden Blvd., Rochester, New York. Defendant also maintains a secondary location at 738 Pre Emption Road, Geneva, New York 14456.

25. Upon information and belief, defendants' patients come from across New York State, including patients from the Northern District of New York.

26. Although defendants University of Rochester Medical Center (and the corresponding Department of Ophthalmology) and Flaum Eye Institute are located in the same building at 210 Crittenden Blvd. in Rochester, New York, the space is segregated amongst each defendant. Each entity has its own waiting room, their own signage, and their own billing systems.

LEGAL BACKGROUND

Medicare

27. Defendants routinely apply for, and receive, reimbursement in connection with Medicare.

28. Medicare is a federally funded program that provides health insurance to people who are sixty-five years and older and people with qualifying disabilities. 42 U.S.C. §§ 426-426a, 1395o.

29. The United States administers the Medicare Program through HHS and its component agency CMS.

30. One part of Medicare, known as "Part B," covers physician and outpatient services for eligible patients. 42 U.S.C. § 1395(k)(a)(2).

31. During the times relevant to this action Defendants were Medicare "providers." As such, Defendants, as a condition of participation in and payment under the

Medicare Program, agreed to abide by Medicare laws, regulations, and program instructions that they would not knowingly submit false claims for payment.

32. Furthermore, it is a universal requirement of the Medicare payment program that all services provided must be reasonable and medically necessary. 42 U.S.C. § 1395y(a)(1)(A); 42 U.S.C. § 1395y(a)(1)(I). Medicare providers may not bill the United States for medically unnecessary services or procedures performed solely for profit of the provider. *Id.*

33. Medicare Part B is funded by insurance premiums paid by enrolled Medicare beneficiaries and contributions from the federal treasury. 42 U.S.C § 1395j. Eligible individuals who are sixty-five or older, or disabled, may enroll in Medicare Part B to obtain benefits in return for payments of monthly premiums as established by HHS. 42 U.S.C. § 1395j. However, payments under Medicare Part B are often made directly to service providers, such as physicians, rather than to the patient/beneficiary. In that case, the provider bills the Medicare Program directly.

34. The United States provides reimbursement for Medicare claims from the Medicare Trust Fund through CMS. To assist in the administration of the Medicare Part B Program, CMS contracts with carriers. 42 U.S.C. § 1395u. Carriers are then responsible for processing the payment of Medicare Part B claims to providers on behalf of CMS.

Defendants' Statements, Certifications, and Submissions to Medicare

35. In order to bill Medicare Part B, a provider must submit an electronic or hard-copy claim form called a "CMS 1500" form to the carrier. When the CMS 1500 is submitted, the provider certifies that the services for which payment is sought were "medically indicated and necessary for the health of the patient."

36. Prior to submitting reimbursement claims electronically to the Part B contractor, providers must agree that they will submit claims that are accurate, complete, and truthful. Providers also must agree that the provider identification number submitted on each reimbursement claim constitutes the provider's electronic signature and an assurance that the services were provided as billed.

37. For a CMS 1500 claim to be paid by the Medicare Part B Program, the claims must identify each service rendered to the patient/beneficiary by the provider by a corresponding code for such services listed in the American Medical Association (AMA) publication called the Current Procedural Terminology (CPT) Manual. The CPT is a systematic listing of codes for procedures and services performed by or at the direction of a physician. Each procedure or service is identified by a five digit numeric CPT code. Medicare establishes a fee reimbursement under Part B for each procedure described by a CPT code.

38. At all relevant times, defendants submitted claims to a fiscal intermediary. In turn, the fiscal intermediary made payments on those claims that appeared to be eligible for reimbursement under the Medicare Part B Program.

39. In order to do so, Defendants entered into an Electronic Data Interchange ("EDI") Enrollment Agreement.

40. Upon information and belief, as part of that EDI Enrollment Agreement, Defendants agreed to submit claims that are accurate, complete, and truthful. In signing the EDI Enrollment Agreement, Defendants acknowledged in substance that all claims would be paid by federal funds, and that the submission of a claim is a claim for payment under Medicare.

41. Additionally, in order to be paid for services furnished to Medicare beneficiaries, a provider must file an annual cost report with the relevant Intermediary.

42. Upon information and belief, Defendants submitted cost reports to their Intermediary each year during the relevant period.

43. Upon information and belief, the cost reports submitted by Defendants contained the following acknowledgments:

> MISREPRESENTATION OR FALSIFICATION OF ANY INFORMATION CONTAINED IN THIS COST REPORT MAY BE PUNISHABLE BY CRIMINAL, CIVIL AND ADMINISTRATIVE ACTION, FINE AND/OR IMPRISONMENT UNDER FEDERAL LAW. FURTHERMORE, IF SERVICES IDENTIFIED IN THIS REPORT WERE PROVIDED OR PROCURED THROUGH THE PAYMENT DIRECTLY OR INDIRECTLY OF A KICKBACK OR WERE OTHERWISE ILLEGAL, CRIMINAL, CIVIL AND ADMINISTRATIVE ACTION FINE AND/OR IMPRISONMENT MAY RESULT.

44. In order to submit a complete cost report, and thereby remain eligible to receive Medicare payments, an officer or director on behalf of defendants was required to make certain certifications that defendants complied with all applicable laws and regulations.

45. Defendants were required to certify that its cost report as filed with its Intermediary was (1) truthful, i.e., that the cost information contained in the report is true and accurate; (2) correct, i.e., that it was entitled to reimbursement for the reported costs in accordance with applicable instructions; (3) complete, i.e., that the cost report is based upon all information known to defendants; and (4) that the services identified in the cost report were not corrupted by kickbacks, were billed in compliance with the Stark Statute, and were otherwise provided in compliance with all applicable health care laws and regulations.

46. Upon information and belief, an officer or director of defendants signed and submitted an annual cost report for defendants.

Medicaid

47. Defendants routinely apply for, and receive, reimbursement in connection with Medicaid.

48. Medicaid, a health insurance program created by Title XIX of the Social Security Act of 1965, authorizes grants to States for medical assistance to children, blind, aged and disabled individuals whose income and resources are not sufficient to meet the costs of necessary medical care. 42 U.S.C. § 1396; 42 C.F.R. § 430.0; *see also* 42 U.S.C. §§ 1396-1396v. Thus, Medicaid primarily benefits people and families with low incomes and disabled individuals. Medicaid is a means-tested program that is jointly funded by the States and the Federal Government and is managed by the States. The amount of Federal funding in a State's program is determined by a statutory formula set forth in 42 U.S.C. §§ 1396b(a) and 1396d(b).

49. Upon information and belief, Medicaid provides health care coverage for approximately 53 million people. Each State administers its own Medicaid program while CMS monitors the State-run programs and establishes requirements for service delivery, quality, funding and eligibility standards. States provide up to half of the funding for the Medicaid program.

50. A State that elects to participate in Medicaid must establish a plan for providing medical assistance to qualified beneficiaries. 42 U .S.C. § 1396a(a)-(b); *see also* 42 C.F.R. Part 430, Subparts A and B; CMS State Medicaid Manual § 13025. In exchange, the Federal Government, through CMS, pays to each participating State the Federal portion of the expenditures made by the participating State to providers and ensures that the States comply with minimum standards in the administration of Medicaid. 42 U.S.C. §§ 1396,

1396a, and 1396b.

51. The State of New York has elected to participate in Medicaid, has established a State plan under Medicaid and has promulgated regulations that implement the State plan. N.Y. Soc. Serv. L. §§ 363 *et. seq.*; 10 N.Y.C.R.R. Parts 85-86; 18 N.Y.C.R.R. Part 360. The New York State Department of Health (hereinafter "NYSDOH") is the sole Medicaid agency that has contracted with HHS to administer or supervise Medicaid in New York State. N.Y. Pub. Health L. § 201.1(v); *see also* 42 U.S.C. § 1396a(a)(5); 42 C.F.R. § 431.10(b).

52. Federal Medicaid law does not set precise requirements and States are free to set payment rates. Individuals or entities that provide services to Medicaid beneficiaries in New York submit claims for payment to NYSDOH or its local delegate agency. 42 C.F.R. § 430.0. Payments are made based on types and ranges of services, payment levels for services and administrative and operating procedures established by the State in accordance with Federal laws, statutes and rules. *Id.*

Defendants' Statements, Certifications, and Submissions to Medicaid

53. In New York, a provider that treats Medicaid beneficiaries may only submit claims for reimbursement for services that have been provided in compliance with Title 18 of the New York Code of Rules and Regulations. 18 N.Y.C.R.R. § 504.6(d). By enrolling in the New York State Medicaid program, a provider agrees to comply with the rules, regulations and official directives of the NYSDOH. 18 N.Y.C.R.R. § 504.3(i).

54. 18 N.Y.C.R.R. § 515.2 provides, in pertinent part:

> (a) Unacceptable practices under the medical assistance program. (1) . . . conduct by a person which is contrary to the official rules and regulations of [NYSDOH]; (2) . . . conduct by a person which is contrary to the published fees, rates, claiming instructions or procedures of [NYSDOH]; (4) . . . conduct

> by a person which is contrary to the regulations of [HHS] promulgated under [Title XIX]; (b) Conduct included. An unacceptable practice is conduct which constitutes fraud or abuse and includes the practices specifically enumerated in this subdivision. (1) False claims: (i) Submitting, or causing to be submitted, a claim or claims for unfurnished medical care, services or supplies; (2) False statements: (i) making or causing to be made any false, fictitious or fraudulent statement or misrepresentation of material fact in claiming a medical assistance payment. or for use in determining the right to payment; (3) Failure to disclose: Having knowledge of any event affecting the right to payment of any person and concealing or failing to disclose the event with the intention that a payment be made when not authorized, or in a greater amount than due.

55. At all times relevant hereto, Defendants were required to and did submit an enrollment application to participate in the New York State Medicaid Program.

56. At all times relevant hereto, Defendants were required to and did submit along with such applications a certification that they would comply with all NYSDOH and Medicaid regulations, as well as impliedly certifying compliance with such regulations by submitting claims for reimbursements.

57. Additionally, Federal regulations require compliance with state rules and regulations as a condition of payment of the Federal share of Medicaid. *See* 2 C.F.R. § 225 App. A(C)(1)(c).

58. The New York Office of the Medicaid Inspector General ("OMIG") is tasked with regulating, auditing, and monitoring providers in the New York Medicaid system. A large portion of OMIG's work involves identifying and recovering fraudulent and improper payments.

59. As an integral part of achieving its missions, OMIG enforces regulations requiring Medicaid providers to adopt and implement effective compliance programs.

60. Social Services Law § 363-d and 18 NYCRR Part 521 require providers who furnish services under Medicaid, or who submit claims for care, services, or supplies on

behalf of Medicaid beneficiaries, as a substantial portion of their business operations to adopt and implement compliance programs. A "substantial portion" of business is defined in 18 NYCRR Part 521.2(b) as a provider who receives, or is expected to receive, at least $500,000 per year from Medicaid.

61. According to OMIG, an "effective" compliance program is to include " . . . internal systems to prevent, or identify, disclose and address, inappropriate conduct, poor care, or improper billing." *See* 2011 New York State Office of the Medicaid Inspector General Work Plan, page a.

62. The New York Medicaid Program, through the Department of Health of the State of New York, publishes policy manuals for providers within the New York State Medicaid Program. *See* https://www.emedny.org/providermanuals/AllProviders/index.aspx.

63. Pursuant to the "Information for All Providers: General Billing" manual circulated by the New York State Medicaid Program, providers must also certify that they "furnished or caused to be furnished the care, services and supplies itemized in accordance with applicable federal and state laws and regulations."

64. According to the General Billing information, providers also certify that they agree to abide by:

> all rules, regulations, policies, standards, fee codes, and procedures of the DOH as set forth in Title 18 of the Official Compilation of Codes, Rules, and Regulations of New York State and other publications of the Department., including Provider Manuals and other official bulletins of the Department.

65. At all times relevant hereto, Defendants certified that they would comply with all New York State Department of Health and Medicaid rules and regulations, including those contained within the "Information for All Providers: General Policy" and "Information for All Providers: General Billing" manuals.

66. As a result of receiving over $500,000 per year from Medicaid, Defendants further certified at all relevant times that they had an effective compliance program as required by 18 NYCRR Part 521.3.

The False Claims Act, NYSFCA, and the Patient Protection and Affordable Care Act

67. Under the federal False Claims Act, an entity is liable to the United States if it knowingly makes, uses or causes a false statement or record to improperly avoid or decrease an obligation to pay the United States. 31 U.S.C. § 3729(a)(1)(G).

68. "Knowing," within the meaning of the FCA, is defined to include reckless disregard and deliberate indifference to the truth or falsity of the information. *Id.* § 3729(b)(1). Additionally, "obligation" is defined under the statute as the "retention of any overpayment." § 3729(b)(3).

69. Under the NYSFCA, an entity is liable to the State if it knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay the State. N.Y. Fin. Law § 188(1)(h).

70. "Knowing," within the meaning of the NYSFCA, is defined to include reckless disregard, or deliberate ignorance, to the truth or falsity of the information. *Id.* §§ 188(3)(a)(ii), (iii). Additionally, "obligation" under the statute includes "the retention of an overpayment." *Id.* § 188(4).

71. Section 6402(a) of the Patient Protection and Affordable Care Act ("ACA"), passed March 1, 2010, requires providers to report and return overpayments of Medicaid funds within 60 days after the overpayment is identified. H.R. 3590, 111th Cong. § 6402(a). An "overpayment" under that statute includes funds received from Government Programs pursuant to which the recipient was not entitled. *Id.* The ACA also makes it a

violation of the FCA, as a "reverse false claim," to fail to return the overpayment. *Id.*

72. Failure to return any overpayment, such as each of the claims on which Defendant received an overpayment from Medicaid, constitutes a reverse false claim actionable under section 3729(a)(1)(G) of the False Claims Act and under State Fin. Law § 189(1)(h) of the NYSFCA.

FACTUAL BACKGROUND

73. During the course of her employment with defendant Flaum Eye Institute, Relator Jane Doe has experienced first-hand a culture of pursuing profits over compliance.

74. Defendants have developed several schemes designed to defraud Medicare and Medicaid which Relator details below.

Upcoding of Modifier 25

75. For years, defendants have received larger reimbursements from Medicare than they are actually entitled to by improperly upcoding claims using "Modifier 25."

76. Certain eye conditions are treated by having a patient undergo an eye injection procedure. For example, patients with macular degeneration can be treated by a physician administering drugs via intravitreal injections.

77. Medicare Part B reimburses hospitals and physicians for certain eye injection procedures, such as intravitreal injections, performed in the hospital outpatient or outpatient setting.

78. In addition to reimbursement for the intravitreal injection procedure, physicians are also eligible for an additional payment for separate evaluation and management ("E&M") services. The additional payment is intended to reimburse the provider for both the operational expenses of performing the service in the outpatient setting

as well as the provider for their professional services.

79. An E&M service has three required elements in which the physician must (1) review the patient's history; (2) examine the patient; and (3) make a medical decision to manage the illness.

80. Generally, providers are not entitled to payment for a separate E&M service rendered on the same day as an intravitreal injection. However, in some circumstances, Modifier 25 allows additional payment for a separate E&M service that is rendered on the same day as an injection.

81. Under the CMS rules outline in the Medicare Claims Processing Manual, Pub. No. 100-04, chapter 12, section 30.6.6(B), Medicare will only pay for same day E&M services that are significant, separately identifiable, and above and beyond the usual preoperative work of the eye injection procedure.

82. In other words, upcoding occurs if a provider uses Modifier 25 to claim payment for a E&M service when the service rendered was not significant, was not separately identifiable, and was not above and beyond the care usually associated with the procedure.

83. Despite the requirements that Flaum bill for services that are separately identifiable, significant, and above and beyond the usual service, defendants have schemed to defraud the Government by systemically billing Modifier 25 for virtually all patients that receive an intravitreal injection.

84. Upon information and belief, despite routinely billing the modifiers, many of the Flaum physicians have made no notation in the medical records supporting the criteria for using Modifier 25.

85. In addition to knowingly submitting upcoded claims, defendants have also

audited ophthalmology claims involving Modifier 25 and identified known overpayments where the medical records did not support Modifier 25.

86. In fact, the University of Rochester Medical Center's Compliance Department warned the Flaum providers that the Modifier 25 claims did not meet the required criteria. However, the Flaum providers ignored this warning and continued billing (and continue to do so) the Modifier 25 incorrectly.

87. Despite identifying known overpayment for Modifier 25 services, Defendants failed to notify CMS to report and return any improper payments, thereby violating section 3729(a)(1)(g) of the False Claims Act and § 188(1)(h) of the NYSFCA and as required by the Patient Protection and Affordable Care Act.

Defendants Illegally Divert 340B Drugs to Flaum Eye Institute and Improperly Identify the Place of Service as Hospital Outpatient

88. For years, defendants have improperly diverted highly discounted 340B drugs from Strong Memorial Hospital to the Flaum Eye Institute providers. Defendants have done so despite the fact that Flaum's office space is an outpatient office setting that is ineligible for 340B pricing. By doing so, defendants have defrauded Medicaid of likely millions of dollars by providing Flaum a subsidy for which it is not entitled. Furthermore, although Flaum identifies the place that the drugs are administered as hospital outpatient, it is in fact an office setting.

89. The Veterans Health Care Act of 1992 established the 340B Program in section 340B of the Public Health Service Act ("PHSA"). The 340B Program requires drug manufacturers participating in Medicaid to provide discounted outpatient drugs to certain health care facilities, referred to as "covered entities."

90. Section 340B limits the cost of covered outpatient drugs to certain federal

grantees, federally-qualified health center lookalikes and qualified disproportionate share hospitals. Entities that participate in the 340B program receive substantial savings on pharmaceuticals. The purpose of the 340B program is to provide drugs at significantly reduced prices to "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384(II), at 12 (1992).

91. The 340B Program is run by the Health Resources and Services Administration ("HRSA"), which is part of the Department of Health and Human Services.

92. To participate in the 340B Program, covered entities must register with the HRSA, the agency responsible for administering the program. Covered entities must sign an annual certification stating that they comply with the 340B program requirements.

93. The list of "covered entities," which is enumerated under 42 U.S.C. § 256b(a)(4) includes, but is not limited to, facilities such as disproportionate share hospitals, children's hospitals, critical access hospitals, cancer hospitals, and sole community hospitals.

94. Additionally, a covered entity may dispense 340B purchased drugs only to eligible patients.

95. According to HRSA's patient definition, an individual is an eligible patient only if:

> (1) the covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care;
>
> (2) the individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g., referral for consultation) such that responsibility for the care provided remains with the covered entity; and

> (3) the individual receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding or Federally-qualified health center look-alike status has been provided to the entity.

96. An individual will not be considered a "patient" of the entity for purposes of 340B if the only health care service received by the individual from the covered entity is the dispensing of a drug or drugs for subsequent self- administration or administration in the home setting.

97. Dispensing 340B purchased drugs to ineligible patients, a practice known as diversion, is prohibited. "[A] covered entity shall not resell or otherwise transfer [a 340B] drug to a person who is not a patient of the entity." Sec. 340B(a)(5)(B) of the Public Health Service Act.

98. 340B drugs may be shared by a 340B covered entity with another entity under certain very limited circumstances. For instance, a free standing clinic that is provider-based or "under arrangements" with a 340B covered entity may share 340B drugs and pricing if certain conditions are met. For example, a provider-based entity must operate under the same license of a hospital, be financially and clinically integrated with a hospital, and share medical records. Additionally, provider-based entities must inform patients of their hospital affiliation and instruct patients that they will be billed separately for facility and physician charges.

99. Thus, for a health care entity to properly participate in the 340B drug program, not only must the entity itself be considered a "covered entity" under the PHSA, the 340B drugs can only be administered to eligible patients.

100. At all relevant times, defendant Strong Memorial Hospital was a covered entity under the HRSA and therefore can dispense drugs purchased through the 340B program to

eligible patients. Strong Memorial Hospital (and the University of Rochester Medical Center) is registered with HRSA under the 340B Identification Number of DSH330285D.

101. However, Flaum Eye Institute, as a freestanding and financially independent entity, is not eligible to participate in the 340B program. Similarly, 340B drugs purchased by defendant Strong Memorial Hospital may not be diverted to Flaum Eye Institute patients.

102. Despite the fact that Flaum Eye Institute is not eligible for 340B pricing, for years defendants have schemed to defraud Medicaid by purchasing 340B drugs through Strong Memorial Hospital's pharmacy and providing them to Flaum patients.

103. To avoid detection of this practice, defendants have incorrectly billed the place of service of such services as hospital outpatient. In reality, the drug administrations are performed in Flaum's private office setting and not a hospital outpatient setting.

104. Defendant Flaum Eye Institute is a private practice and the Flaum physicians are employees of Flaum and are not paid by or employed by Strong Memorial Hospital.

105. Although Flaum is physically located at the same address and building as the University of Rochester Medical Center's Department of Ophthalmology at 210 Crittenden Blvd. in Rochester, Flaum operates as an independent office.

106. As part of Flaum's scheme to defraud the Government to obtain 340B pricing, Flaum improperly listed the place that the 340B drugs were administered as a hospital outpatient setting. In fact, the drugs were administered in a private practice office setting.

107. Thus, not only does Flaum obtain a fraudulent subsidy by using 340B drugs as a non-covered entity, it further improperly bills the government with the incorrect place of service as a hospital outpatient setting when in fact it is not.

108. For example, a typical Flaum patient may suffer from macular degeneration.

Upon arriving at Flaum's offices, the patient would be treated in Flaum's office space and billed as an office visit under the relevant E&M codes. While still seated in that same treatment chair, Flaum would simultaneously bill for an intravitreal injection as a hospital outpatient service using 340B drugs.

109. Relator is aware that defendants' compliance office repeatedly told Flaum that injection procedures done with 340B drugs must be done in hospital space. However, the Flaum physicians ignored this mandate and have continued to bill drugs as being administered in hospital space despite the fact that the drugs are actually administered in Flaum's office space.

Improper Billing for Use of the Femto Laser

110. Upon information and belief, a Femtosecond ("Femto") laser, which is an advance technology tool for cataract surgery, costs approximately $500,000.

111. Under the relevant Medicare regulations, providers may not bill Medicare to perform covered components of cataract surgery with a Femto laser. In other words, reimbursement does not change depending on whether traditional surgery or a laser is used.

112. Due to the high costs of purchasing a Femto laser coupled with the fact that Medicare does not reimburse for Femto laser procedures, providers typically lose money by purchasing a Femto laser.

113. Providers are prohibited in engaging in tactics referred to as "balance billing" where providers use additional services to essentially bill for the cost of a Femto laser.

114. Despite this prohibition, defendants have engaged in "balance billing" by inappropriately using the differential charge for a premium intra-ocular lens ("Premium IOL") to recover the cost of using the Femto laser.

115. Although defendants bill for a Premium IOL that includes extended post-operation services, defendants fail to provide any additional services that justify a Premium IOL and instead should be billed for as a standard IOL.

116. Shortly after defendants purchased a Femto laser in January 2014, defendants developed a business plan designed to offset the Femto purchase by scheming to inappropriately bill services as Premium IOLs. At the same time, defendants introduced a new fee schedule increasing prices to offset the Femto purchase.

117. As a result of defendants' scheme to engage in "balance billing," defendants have submitted upcoded claims to Medicare.

Lack of Medical Necessity for Cataract Surgeries

118. Cataract surgery is a procedure performed on a cataract, that is to say "a partial or complete opacity on or in the lens of the eye or the capsule of the lens, especially one impairing vision or causing blindness." *Dorland's Illustrated Medical Dictionary* 308 (31st ed. 2007). Surgery, which consists of removal of a cataract and replacement with an intra-ocular lens implant, becomes necessary when a cataract spreads into the visual axis of the eye where light reflects.

119. From approximately 2010 to 2013, defendant Flaum employed a physician, Dr. Yousuf Khalifa, who performed cataract surgeries that lacked medical necessity.

120. Upon information and belief, a large number of the cataract surgeries that Dr. Khalifa performed were not medically necessary. Specifically, the surgeries were not medically necessary because there was sufficient visual acuity and/or not a mature enough cataract that would impact the patient's vision.

121. Instead, this would be an elective procedure that is not covered under

Medicare.

122. Defendants internally investigated and audited the surgeries performed by Dr. Khalifa and ultimately determined that the surgeries had no medical necessity.

123. Therefore, despite identifying known overpayment for services performed by Dr. Khalifa, Defendants failed to notify CMS to report and return any improper payments, thereby violating section 3729(a)(1)(g) of the False Claims Act and § 188(1)(h) of the NYSFCA and as required by the Patient Protection and Affordable Care Act.

FIRST CAUSE OF ACTION
False Claims Act

124. The foregoing allegations are repeated and realleged as if fully set forth herein.

125. Relator seeks relief against Defendants pursuant to the FCA, 31 U.S.C. § 3729, *et seq.*

126. As set forth above, in connection with the foregoing schemes, Defendants knowingly, or with reckless disregard for the truth, presented and/or caused to be presented false or fraudulent claims for payment to the United States, Medicaid, United States agencies and/or entities that were recipients of United States funds.

127. By reason of the foregoing, the United States has been damaged in a substantial amount to be determined at trial, and is entitled to treble damages and penalties as required by law for each violation.

SECOND CAUSE OF ACTION
Reverse False Claims Under the FCA

128. The foregoing allegations are repeated and realleged as if fully set forth herein.

129. Relator seeks relief against Defendants pursuant to the FCA, including pursuant to 31 U.S.C. § 3729(a)(1)(G), *et seq*.

130. As set forth above, in connection with the foregoing schemes, Defendants knowingly, or with reckless disregard for the truth, made, used and/or caused to be made or used a false record or statement to conceal or avoid or decrease an obligation to pay or transmit money or property to the United States.

131. Defendants were under an obligation to return overpayments from the United States.

132. The Patient Protection and Affordable Care Act ("ACA"), passed March 1, 2010, requires providers to report and return overpayments of Medicaid funds within 60 days after the overpayment is identified. H.R. 3590, 111th Cong. § 6402(a). An "overpayment" under that statute includes funds received from Government Programs pursuant to which the recipient was not entitled. *Id*. The ACA also makes it a violation of the FCA, as a "reverse false claim," to fail to return the overpayment. *Id*.

133. Although Defendants were aware of extensive issues with their billing for reimbursements from the United States and Medicaid, not only did they fail to take prospective action to stem the submission of fraudulent bills, they also failed to make timely refunds of overpayments.

134. By reason of the foregoing, the United States has sustained damages in a substantial amount to be determined at trial, and is entitled to a civil penalty as required by law for each violation.

THIRD CAUSE OF ACTION
Violations of the New York False Claims Act

135. The foregoing allegations are repeated and realleged as if fully set forth

herein.

136. Relator seeks relief against Defendants pursuant to the NYSFCA, N.Y. FIN. LAW, §§ 187 *et seq.*

137. As set forth above, in connection with the foregoing schemes, Defendants knowingly, or with reckless disregard for the truth, presented and/or caused to be presented false or fraudulent claims for payment to the State of New York, Government agencies and/or entities that were recipients of Government funds.

138. By reason of the foregoing, the Government has been damaged in a substantial amount to be determined at trial, and is entitled to damages and penalties as required by law for each violation.

FOURTH CAUSE OF ACTION
Reverse False Claims Under NYSFCA

139. The foregoing allegations are repeated and realleged as if fully set forth herein.

140. Relator seeks relief against Defendants pursuant to the NYSFCA, N.Y. FIN. LAW, § 189(1)(h).

141. As set forth above, in connection with the foregoing schemes, Defendants knowingly concealed or knowingly and improperly avoided or decreased an obligation to pay or transmit money to the State of New York.

142. Knowing concealment, avoidance or decrease of an obligation to pay or transmit money to the State of New York was made or done knowingly, as defined in State Fin. § 188(3)(a).

143. By reason of the foregoing, the State of New York has been damaged in a substantial amount to be determined at trial, and is entitled to damages and penalties as

required by law for each violation.

WHEREFORE, Relator, on behalf of himself as well as the United States and the State of New York, requests the following relief:

a. A judgment against Defendants in an amount equal to all damages due to the Government, including treble damages, pursuant to the FCA and/or NYSFCA;

b. A judgment against Defendants for all civil penalties due to the Government for each of Defendants' violations of the FCA and/or NYSFCA;

c. That Relator recover all costs of this action, with interest, including the cost to the Government for its expenses related to this action;

d. That Relator be awarded all reasonable attorneys' fees in bringing this action;

e. That in the event the United States Government proceeds with this action, Relator be awarded an amount for bringing this action of at least 15% but not more than 25% of the proceeds of the action;

f. That in the event the United States Government does not proceed with this action, Relator be awarded an amount for bringing this action of at least 25% but not more than 30% of the proceeds of the action;

g. That a trial by jury be held on all issues so triable;

h. An award of pre-judgment interest; and

i. Such other relief to Relator and/or the United States of America and/or the State of New York as this Court may deem just and proper.

PLAINTIFF DEMANDS A JURY TRIAL.

Dated: March 9, 2015

THOMAS & SOLOMON LLP

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